Device for collection of uncontaminated urine from children

Description

The present invention refers to a device used for collection of uncontaminated urine samples from small children.

The purpose of the invention is mainly to create a disposable device that solves the problem with bacterial contamination when collecting urine samples from children. The device should furthermore be easy to use and be manufacturable at a cost that does not substantially exceed the manufacturing cost of the products used today.

Infection of the urinary tract is a relatively common and potentially serious disease, especially in children. Urinary tract infection is diagnosed by demonstrating growth of bacteria in the urine. Crucial for the reliability of such analysis, is that the enteric bacteria that normally colonize the skin of the uro genital area do not contaminate the urine sample. The most reliable ways to obtain an uncontaminated urine sample is by percutaneus bladder tap, urethral catheterisation or by midstream specimen. These methods are, however, in many cases not suitable. Percutaneus bladder taps as well as urethral catheterisation are proportionately traumatic procedures and midstream specimens are for practical reasons difficult to obtain, above all from small children since they usually are not able to produce a urine sample on demand. Ordinarily, a collecting bag attached to the genital area is therefore used. This allows the children to move around and does not imply any significant discomfort to them.

The collecting devices that are currently used are designed as a plastic bag. It has an opening on one side that is attached to the genital area with an adhesive material.

Examples of such devices can be found in patents GB1051875, WO0000111, SE333792, US3406690, US3523537 and US3200415. Alternative designs are presented in US3918433 and GB2163656. Common to the mentioned patents is however that they mainly focus on the attachment and collection functions of the device and that they do not address the risk of contamination sufficiently. Other patents that adress this problem can be found in US4557274, US4492258 and US3881465.

Using above mentioned devices, a substantial part of the samples is rendered useless and has to be resampled since they have been contaminated with non relevant bacteria. This leads to delay and difficulties in diagnosing and treatment, yielding over- as well as under diagnosing, the consequences being, apart from higher costs and ineffective use of medical care resources, unnecessary suffering for the patients and their parents.

When using conventional devices the main contamination occurs when the fluid on its way to the container collects non relevant bacteria, partly directly from the skin, partly from those parts of the collecting device that have been in direct contact with it.

In order to avoid this, the present invention is furnished with a collecting bag whose opening excludes all direct contact between the skin and the inner face of the collecting bag. The opening is furthermore initially sealed with for example a water soluble adhesive material or substance. In the moment of voiding this is dissolved by the fluid so that the inlet of the collecting bag opens. The fluid that initially is prevented from reaching the collecting bag is almost instantly absorbed by the absorbing material.

This design renders a rinsing effect of those surfaces that the initial fluid is exposed to, simultaneously preventing non relevant bacteria, being flushed along, from reaching the collecting bag.

Detailed description

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Fig.1: Device viewed from above according to manufacturing suggestion 1.
Fig.2: Device viewed from aside according to manufacturing suggestion 1.
Fig.3: Manufacturing suggestion 1. Non folded work piece viewed from above.
Fig.4: Device viewed from aside according to manufacturing suggestion 2.

All figures and descriptions relate to the user point of view. The expression "from above" means consequently the side the user sees from above, that is the side that, when in use, is attached to the body.

The expression "uncontaminated" here means a contamination with bacteria that is significantly below the lower value for significant bacteriuria applied to this kind of urine analysis.

The invention consists of a collecting bag (1) with an absorbing material (7) placed around an opening (4) on the upper face of the device. The device is worn with the absorbing layer (7) against the body, placed so that said opening (4) is situated opposite to the urethral opening. Fluid reaches the collecting bag (1) via said opening (4) where after it passes a tube shaped channel (5), initially closed by a delay mechanism (9) consisting of for example a water soluble adhesive material or substance. When the urine reaches said opening (4) instant flow to the collecting bag (1) is prevented due to the adhesive substance (9) placed in the

channel (5), whereby the fluid is absorbed by the absorbing material along with a major part of the bacteria that have contaminated the transport route of the fluid. Thereafter the adhesive substance (9) is dissolved so that said channel (5) is opened, where after the remaining fluid is able to reach the collecting bag (1), mainly uncontaminated.

According to the first manufacturing suggestion (fig. 1, 2 and 3) the device is shaped as a bag similar to the bags used today. According to said suggestion it can be manufactured from a single piece of plastic sheet material (fig. 3). When the opening (4) has been made and the delay mechanism (9) has been positioned on its intended place, the work piece is folded in two places (10) and welded together (11) according to fig. 3. Thereafter, the absorbing layer (7) and the adhesive surface (8) is mounted.

According to the second manufacturing suggestion (fig. 4) the container of the device (1) is attached to the lower side of yet another layer (12). This layer can for example be in the form of a diaper and its main purpose is to function as an alternative attachment device for the container. Said layer (12) have, in this case, been equipped with those details and functions witch were placed directly on the upper side of the container in the previous suggestion.

The device comprises a container (1) with sufficient volume to be able to contain the appropriate amount of urine. The container can for example be rectangular, oval or anatomically shaped. It can be manufactured from one or several pieces of material. Said container (1) can for example be made of a fluid impermeable plastic film made of a thermoplastic material like polyethylene or polypropylene. The container (1) can be welded, glued or otherwise assembled in any other way known to humanity.

The inlet of the container (1) starts with an opening (4) in a layer of plastic material (2) that has been attached to a lower layer (3) so that a tube like channel (5) is formed. These layers can be made from the same work piece as the container, according to manufacturing suggestion 1 (fig. 1, 2 and 3), or from 2 different pieces, according to manufacturing suggestion 2 (fig. 4).

The opening (4) is situated at the most appropriate place of the device depending on the design and should be designed so that it facilitates the opening of said channel (5). It should be as small as possible because of the risk of contamination, yet large enough to render a correct placement of the device when applied to the body. Said channel (5) can be of different sizes and can be located anywhere within said opening (4).

The aperture of the container consists of said channel (5) witch entrance consists of a funnel shaped flange (6). This flange should be designed so that it leads the fluid towards said channel (5) without preventing the initial part of the fluid from reaching the absorbing layer (7). One possible design is presented in fig 1,2 and 3, where the upper plastic layer (2) has been attached (11) to the lower (3), so that the flange extends around the opening (4) to its opposite side where the lower layer (3) has been attached to the outer rim of the upper layer (2).

The channel (5) is initially closed in a way that enables it to open automatically shortly after coming in contact with the fluid. Such a delaying mechanism (9) could be accomplished with a suitable water soluble substance or material that dissolves within a specified timeframe. This substance or material can consist of glue, an adhesive polymer or any other known substance or material with preferred characteristics. It should however not contain any substances that affect the quality of the sample in any significant way.

On the upper side of the container, (1) an absorbing layer (7) is placed close to the opening (4). This material could e.g. consist of cellulose fibres, viscose fibres or super absorbing synthetic polymers such as polyacrylate. The layer can be designed in any form, for example round, oval or rectangular and should be placed where it best serves its function.

It can also be designed according to gender and equipped with an anatomically shaped contour to enhance fitting. The material should be chosen and designed so that a certain amount of fluid is absorbed within a predefined timeframe. It can also be surrounded by a waterproof barrier to prevent too much fluid from being absorbed or reach the adhesive surface that attaches the device to the body. This barrier can for example be manufactured from a surface treated non woven material or from any other suitable material.

The absorbing layer (7) can be covered with a surface layer that only permits fluid to flow in one direction, so that the already absorbed fluid is prevented from leaking back and thereby reaching the container. This layer can consist of any known appropriate material available on the market and can for example consist of a non woven material that has been surface treated, laminated or prepared in any other way and thereby achieve preferred characteristics.

The device can also be provided with one or several adhesive surfaces (8) partly to keep the device in place, partly to prevent leakage. The adhesive surfaces (8) can consist of any waterproof adhesive substance of those commonly used in this context. Especially suitable are those of hydrocolloid or hydrogel type. The surfaces can be of any shape and number and can be placed anywhere on the device. The surfaces can be supplied with a protective sheet that can be removed before use.